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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,918	12/28/2001	Rajiv Shah	047711-0293	2208

7590

06/18/2003

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EXAMINER

PAK, YONG D

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,918

Applicant(s)

SHAH ET AL.

Examiner

Yong D Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 25-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-43 are pending.

Election/Restrictions

Applicant's election of Group I (claims 1-24) in Paper No. 8 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 25-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Witt et al.

Witt et al. (form PTO-892) teach a method of formulating or making a mutant glucose oxidase gene by obtaining a glucose oxidase gene, creating at least one mutated glucose oxidase, introducing said mutated glucose oxidase gene into vectors, inserting the vector into host organisms, growing colonies of the host organism and screening the colonies for desirable properties (page 554). Therefore, the teachings of Witt et al. anticipate claims 1 and 20.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wohlfahrt et al. in view of Shtelzer et al. and Bylina et al.

Wohlfahrt et al. (form PTO-892) teach the active center of an *Aspergillus niger* glucose oxidase (pages 973-976). Wohlfahrt et al. teach residues that are in the active center as well as some mutant glucose oxidases (page 974). For example, Met-561, His-516 and His-559 are amino acids that are involved in binding FAD to glucose oxidase. Met-561 is a target for peroxide because methionines are easily oxidized by peroxide. Also, these three residues are peroxide targets because they are involved in binding glucose to FAD and oxidation of the residues result in deactivation of the glucose oxidase.

The difference between the teaching of Wohlfahrt et al. and the instant invention is that the reference of Wohlfahrt et al. does not teach a method for making mutant

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glucose oxidases that are resistant to oxidation and determining whether colonies comprising the mutant protein have peroxide resistant properties or are less susceptible to oxidation.

Shtelzer et al. (form PTO-892) teach a biosensor comprising an immobilized glucose oxidase (abstract). Shtelzer et al. and art teach that glucose oxidases are susceptible to peroxide dependent inactivation (Greenfield et al., page 111 and Binyamin et al., abstract) and that this instability is one problem in using glucose oxidase in biosensors (Shtelzer et al., abstract,). It is also well known in the art that modification of oxidizable amino acids in a protein decreases the protein's susceptibility to peroxide dependent inactivation, especially residues in or around the active site (U.S. Patent 5,824,532, Column 2 and Estell et al., page 6518).

Bylina et al. (U.S. Patent 5,914,245 – form PTO-892) teach a method of creating at least one mutated glucose oxidase gene using error-prone PCR or a gene-shuffling technique as well as generating multi generations of mutants (Columns 14-19). Protein purification methods as described in claims 11-18 are very well known and routinely performed in the art (Witt et al., page 554).

Bylina et al. teach a method of screening colonies and determining kinetics and spectral data (Columns 2 through 4). The method of Bylina et al. employs fluorescence in its assays and various colored products (Columns 8-12). In the state of the art, there are many known colored products that can be used, including Leo Crystal Violet available through Aldrich (Aldrich Catalog 1998-1999).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make mutant glucose oxidases, either randomly by PCR, as taught by Bylina et al., or by site-directed mutagenesis at oxidizable amino acids at or near the active center as taught by Wohlfahrt et al. and using the mutant glucose oxidase as an immobilized protein in a biosensor as taught by Shtelzer et al. It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to screen colonies containing mutant glucose oxidases for a functional protein and one having resistance to oxidation by peroxide using the method taught by Bylina et al. The motivation of making mutant glucose oxidases having reduced susceptibility to oxidation is to increase the stability and prolong its activity, especially its use in biosensors. One of ordinary skill in the art would have had a reasonable expectation of success since site-directed and random mutagenesis is routinely performed in the art and Bylina et al. teach successful screening assays of colonies containing mutant proteins.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

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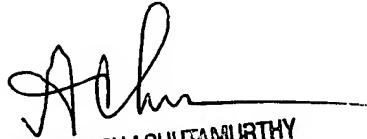
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong D. Pak
Patent Examiner

June 10, 2003



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